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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,963

08/15/2006

Paolo Alberto Veronesi

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STANDLEY LAW GROUP LLP

6300 Riverside Drive

Dublin, OH 43017

EXAMINER

LOVE, TREVOR M

ART UNIT

PAPER NUMBER

1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,963	Applicant(s) VERONESI, PAOLO ALBERTO	
	Examiner TREVOR M. LOVE	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 2, 15 and 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-14, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/28/2009, 08/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 15, and 18-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II and III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/05/2010.

Claims 1-31 are pending.

Claims 2, 15, and 18-31 are withdrawn.

Claims 1, 3-14, 16, and 17 are currently under consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 08/17/2006 and 08/28/2009 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claims 8 and 12 the terms "optimally" and "preferably" render the claims indefinite because it is unclear whether the limitations following the phrases are part of the claimed invention. See MPEP § 2173.05(d).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation of optional quantities, and the claim also recites optimal quantities which are the narrower statements of the range/limitation.

Claim 12 recites that the dispensing volume amounts are "preferable", therefore, it is unclear the extent, if any, said recitation imparts a limitation on the claimed invention.

Claim Objections

Claim 17, while not suffering from the same indefiniteness as claim 12 (in view of the clarifying language of claim 17) directly depends from indefinite claim 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-12, 14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference).

Pinza teaches an aqueous mouthwash or oral spray (see entire document, especially page 3, lines 22-23 and claim 1). Said composition comprising tromethamine

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and a salt of diclofenac, wherein the pH of the composition is between 7 and 8 (see entire document, for instance claim 1). Said composition further comprises sweeteners such as sodium saccharinate, sorbitol, xylitol (see entire document, for instance claim 3). Said composition further comprises a preserving agent, specifically sodium benzoate, methyl p-hydroxybenzoate, or propyl p-hydroxybenzoate (see entire document, for instance claim 4). Said diclofenac is taught as being present in an amount of 0.1 to 0.2% (see entire document, for instance claim 1, also note percentages in table 1 of instant specification). Said tromethamine is exemplified as being present in an amount of approximately a third of that of the diclofenac (see for entire document, for instance page 2, lines 13-17), note that the instant claims utilize the term "about" with regard to the amount of tromethamine present.

Pinza fails to directly teach that the non-steroidal anti-inflammatory drug is flurbiprofen.

Caldwell teaches an oral composition comprising a non-steroidal anti-inflammatory, specifically, either diclofenac, flubiprofen, naproxen, or ketoprofen (see entire document, for instance claims 1 and 3). Caldwell further teaches the use of TRIS (tromethamine) buffer in said composition (see entire document, for instance examples 9 and 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the flubiprofen of Caldwell in the invention of Pinza. One would have been motivated with a reasonable expectation of success to either utilize the flubiprofen in place of the diclofen, or utilize the flubiprofen in combination with the

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diclofen since it is known both to utilize a known compound for its known purpose and to combine two components taught for the same purpose in order to arrive at a third composition for the exact same purpose. It is noted that MPEP 2144.07 states “[t]he selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) [...] “Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle.” 325 U.S. at 335, 65 USPQ at 301.)”. The MPEP further states in 2144.05: ““It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

With regard to the specific amounts of the components, it is noted that MPEP 2144.05 states: “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997).

With regard to the limitation of a dosing pump, Pinza teaches a spray composition, wherein it is noted that spray compositions must have a dosing pump in order to spray the composition. Therefore, though Pinza fails to directly state the nature of the dosing pump, a dosing pump must necessarily be present.

With regard to the exact amount per dose, it is noted that the amount of the composition being utilized is an intended use which one would readily vary depending on the desired treatment and patient (i.e. gender, size, etc).

Claims 1, 3-14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference) as applied to claims 1, 3-12, 14, 16, and 17 above, and further in view of Lundberg et al (U.S. Patent number 6,013,281, patent issued Jan. 11, 2000).

The teachings of Pinza and Caldwell are set forth above.

Pinza fails to directly teach that the composition can comprise either D-glucamine or meglumine.

Lundberg teaches that trometamine, meglumine, and at least one other D-glucamine are all known organic buffer compounds useful in pharmaceutical compositions (See entire document, for instance column 6, lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize any one of, or a combination of trometamine, meglumine, or the at least one other D-glucamine in the invention of Pinza in view of Caldwell. One

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would have been motivated to do so since it is known both to utilize a known compound for its known purpose and to combine two components taught for the same purpose in order to arrive at a third composition for the exact same purpose. It is noted that MPEP 2144.07 states “[t]he selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) [...] “Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle.” 325 U.S. at 335, 65 USPQ at 301.)”. The MPEP further states in 2144.05: ““It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643